

Application No.: 10/057,667
Amendment and Response dated March 11, 2004
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Remarks/Arguments:

Introduction

Claims 1-26 are pending. Claims 1, 8 and 17 have been amended to further describe the graft material as being non-woven graft material. Support for these amendments may be found in paragraph [0084] of the specification.

Section 102 Rejections

Claims 1, 8, 16, 17 and 23 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,824,040 to Cox et al. (hereinafter “Cox”). Applicant respectfully traverses.

Cox is directed to a prosthesis having diamond shaped elements 73 attached to a strip of liner material 75 by being stitched with a sewing machine to form a ribbon. (Cox, column 12, lines 19-24). The ribbon may then be wound over a mandrel to form the prosthesis. (*Id.*; Fig. 5E.). The diamond shaped elements 73 are formed from a wire which is diagonally disposed across the width of the liner material 75. (See, Cox, Fig. 5E). Further, the liner material is described as a woven material made from yarns. (Cox, column 12, lines 7-11). Thus, Cox describes a plurality diamond shaped elements being sewn onto a strip of woven material.

In contrast to Cox, the invention as presently defined by independent Claim 1 is directed to a method of making a tubular stent/graft assembly. The inventive method of Claim 1 comprises the steps of (i) forming a substantially planar strip and wire assembly comprising non-woven planar graft material formable into a graft and planar stent wire formable into a radially adjustable stent, wherein said wire is attached lengthwise along the length of said planar strip; and (ii) helically winding said substantially planar strip and wire assembly to form said tubular stent/graft assembly.

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In contrast to Cox, the invention as presently defined by independent Claim 8 is directed to a method of making a stent/graft assembly. The inventive method of Claim 8 comprises the steps of forming a substantially planar graft and stent material assembly comprising non-woven graft material and stent material; and winding said substantially planar graft and stent assembly to form said stent/graft assembly.

In contrast to Cox, the invention as presently defined by independent Claim 17 is directed to a method of making a tubular stent/graft assembly. The inventive method of Claim 17 comprises the steps of (i) forming a substantially planar strip and stent assembly comprising planar non-woven graft material formable into a graft and a planar stent formable into a radially adjustable stent, wherein said planar stent is attached along the length of said planar strip; and (ii) helically winding said substantially planar strip and stent assembly to form said tubular stent/graft assembly.

Thus, Cox fails to disclose a planar assembly or strip comprising non-woven graft material as described in independent claims 1, 8 and 17.

Further, Cox fails to disclose a wire being attached lengthwise along the length of a liner because Cox requires diagonally disposed diamond shaped elements sewn to the liner. Thus, Cox fails to disclose the lengthwise wire of claims 1 and 17.

Thus, Cox fails to disclose each and every element of the independent claims 1, 8 and 17. Therefore, Applicant respectfully requests withdrawal of the rejection of independent claims 1, 8 and 17, and all claims dependent therefrom, under 35 U.S.C. §102(e).

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Section 103 Rejections

Claims 1, 8, 16, 17 and 23 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,824,040 to Cox et al. (hereinafter "Cox"). Applicant traverses.

As discussed above, Cox describes a plurality of diamond shaped elements 73 sewn onto a woven planar strip of liner material 75. Cox, however, fails to teach or suggest that its diamond shaped elements may be sewn, or otherwise attached, onto a non-woven planar strip of liner material. In other embodiments, Cox fails to teach its particular stent-grafts may be formed by helically winding planar stent-graft assemblies or are made from non-woven liners. Further, where Cox is silent on the particular construction details of its liner or graft materials, i.e., not specifically describing the graft yarns as being woven, Cox teaches that its stent-grafts are formed from cylindrical grafts with cylindrical reinforcing elements being axially attached thereon. (See e.g., Cox, column 13, lines 6-26). Therefore, Cox fails to teach or suggest the present invention or teaches away from the present invention.

Thus, Cox fails to teach or suggest the invention as presently defined by independent claims 1, 8 and 17. Reconsideration and withdrawal of the rejection of independent claims 1, 8 and 17, and all claims depending therefrom, are therefore respectfully requested.

Claims 1-9, 11-24 and 26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Cox in view of either one of U.S. Patent Nos. 5,928,278 to Shannon et al. (hereinafter "Shannon") or U.S. Patent No. 6,517,571 to Brauker et al. (hereinafter "Brauker"). Applicant respectfully traverses.

The action cites Shannon and Brauker for their disclosure regarding stents having an inner lining and an outer covering. Shannon and Brauker, individually or in combination, fail to teach or suggest forming a planar strip of non-woven graft material and stent material. Further, Shannon teaches that its tubular liner must be first placed on a mandrel, a stent is then

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disposed over the liner, and then the outer cover is disposed over the stent. (Shannon, column 10, line 50, to column 11, lines 13; and Figs. 4b-4f). The liner and cover of Shannon are described as being extruded PTFE. Therefore, Shannon fails to cure the deficiencies of Cox because it fails to teach or suggest that planar strip of its extruded PTFE material and stent components may be formed. Thus, Shannon teaches that its prosthesis, which includes non-woven PTFE grafts, is not to be formed as a planar strip which can be subsequently wound around a mandrel, but requires its graft and stent components to be individually disposed over the mandrel.

While not admitting that Brauker is prior art to the present invention, nevertheless Brauker also fails to cure the deficiencies of Cox. Brauker forms its stent-grafts by first wrapping ePTFE graft material onto a mandrel (See, Brauker, column 9, line 66, to column 10, line 1; and column 10, lines 59-66) or by extruding tubular ePTFE onto a mandrel (Brauker, column 13, lines 13-47). Thus, Brauker fails to teach or suggest the formation of a planar strip of stent-graft material.

Therefore, Shannon and Brauker, individually or in combination, fail to cure the deficiencies of Cox. Further, there is no motivation to combine Cox with Shannon or Brauker. Cox discloses that a diamond shaped member may be sewn onto a woven strip of graft material. Cox fails to teach or suggest that other stent arrangements may be sewn to a planar strip of woven material and subsequently helically wound to form a stent-graft. Shannon and Brauker fail to disclose the diamond shaped configuration of Cox. Thus, one of ordinary skill in the art would not be motivated to combine the references because of their divergent stent and liner and/or cover teachings.

Thus, Cox, Shannon and Brauker, individually or in combination, fail to teach or suggest the invention as presently defined by independent claims 1, 8 and 17. Reconsideration

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and withdrawal of the rejection of claims 1, 8 and 17, and all claims dependent therefrom are respectfully requested.

Claims 10 and 25 are rejected under 35 U.S.C. §103(a) as being unpatentable over Cox in view of either Shannon or Brauker and in further view of U.S. Patent No. 6,361,637 to Martin et al. (hereinafter “Martin”). Applicant traverses.

The Action cites Martin for its teachings of an undulated stent configuration and of a stent wire formed from nitinol. As claim 10 contains neither of these limitations, perhaps the action should have applied Martin to claim 9 instead of claim 10.

In any event, Martin teaches that a stent wire maybe helically wound around a mandrel to form a tubular stent. (Martin, column 13, lines 9-12). Graft material is also placed over a mandrel to form an inner tubular liner. (Martin, column 14, lines 4-6). The tubular stent is then positioned over the inner liner to form a stent-graft. (Martin, column 14, lines 8-10). A flat ribbon PTFE is then wrapped around the exterior surface of the stent. (Martin, column 14, lines 13-17). Thus, Martin forms its prosthesis by individually placing different components of the prosthesis over a mandrel.

Therefore, Martin fails to cure the deficiencies of Cox, Shannon or Brauker because Martin fails to teach or suggest forming a planar strip of stent material and non-woven graft material.

Thus, the invention presently defined by claims 1-26, including claims 10 and 25, are patentably distinct over Cox, Shannon, Brauker and Martin, individually or in combination.

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Summary

Therefore, Applicant respectfully submits that independent claims 1, 8 and 17, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461.

Respectfully submitted,


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